

Message Text

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65

ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-05 CIAE-00 INR-07 NSAE-00

EB-07 COME-00 L-03 PA-02 PRS-01 USIA-15 /056 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EA/PHL:ECHULEN(INFO)

----- 095424

P 022209Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY MANILA PRIORITY

UNCLAS STATE 050857

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, RP

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-211-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

PONTOCAINE HCL (BRAND OF TETRACAINE HCL, USP) NIPHANOID;
100/20 MG AMPULES PER BOX; WINTHROP LABORATORIES, NY,
NY 10016; INJECTABLE.

LOT NUMBERS:

ALL LOT NUMBERS WITH LETTERS "LA" TO "LO", "NA" THROUGH
"NK";

050KO 089NA

057LA 019NB

054LB 020NB

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065LF 070NC

062LJ	083NE	
012LK	084NE	
013LK	085NE	07,
024NA	248NH	003NC
025NA	054LC	
026NA	061LJ	

DISTRIBUTION: FROM 1/1/74 UNTIL 10/1/75.

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVE.
RENSSELAER, NY 12144

RECALLING FIRM:

A.
WINTHROP LABORATORIES
DIV. STERLING DRUG, INC.
90 PARK AVE.
NY, NY 10016

B.
WINTHROP PRODUCTS
90 PARK AVE.
NY, NY 10016

REASON FOR ADVISORY (RECALL):

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES
HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA
ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN
MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANU-
FACTURING PRACTICE REGULATIONS AND THAT THERE WAS A
QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE
MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF
"STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF
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THE INJECTABLE PRODUCTS INVOLVED.

2. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO
DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS OF
THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL
CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON
AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY
ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL

AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY
TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEE AS FOLLOWS:

STERLING PRODUCTS INTERNATIONAL, INC., NAKATI, RIZA,
REPUBLIC OF PHILIPPINES. INGERSOLL

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NNN

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Margaret P. Grafeld
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